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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0017]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Guidance on Validation of Analytical Procedures: Methodology; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Validation of Analytical Procedures: Methodology.'' This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from an identically titled guidance adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and published in the **Federal Register**. The guidance provides recommendations on how to consider various validation characteristics for each analytical procedure included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time.

ADDRESSES: Copies of the final guidance document entitled ''Validation of Analytical Procedures: Methodology'' may be obtained on the Internet from the CVM home page at ''http://www.fda.gov/cvm/fda/TOCs/guideline.html''. Persons without Internet access may submit written requests for single copies of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-

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addressed adhesive label to assist that office in processing your requests. Submit written comments on the final guidance document to the Policy and Regulations Team (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Regarding this guidance: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966, e-mail ''wmarnane@cvm.fda.gov''.

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail ''sthompso@cvm.fda.gov''.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seeking scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary pharmaceutical products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Épizooties (OIE). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee. The VICH Steering Committee is composed of member representatives from the

European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, one representative from industry in Australia/ New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay, and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from an identically titled guidance adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and published in the **Federal Register** of May 19, 1997 (62 FR 27464).

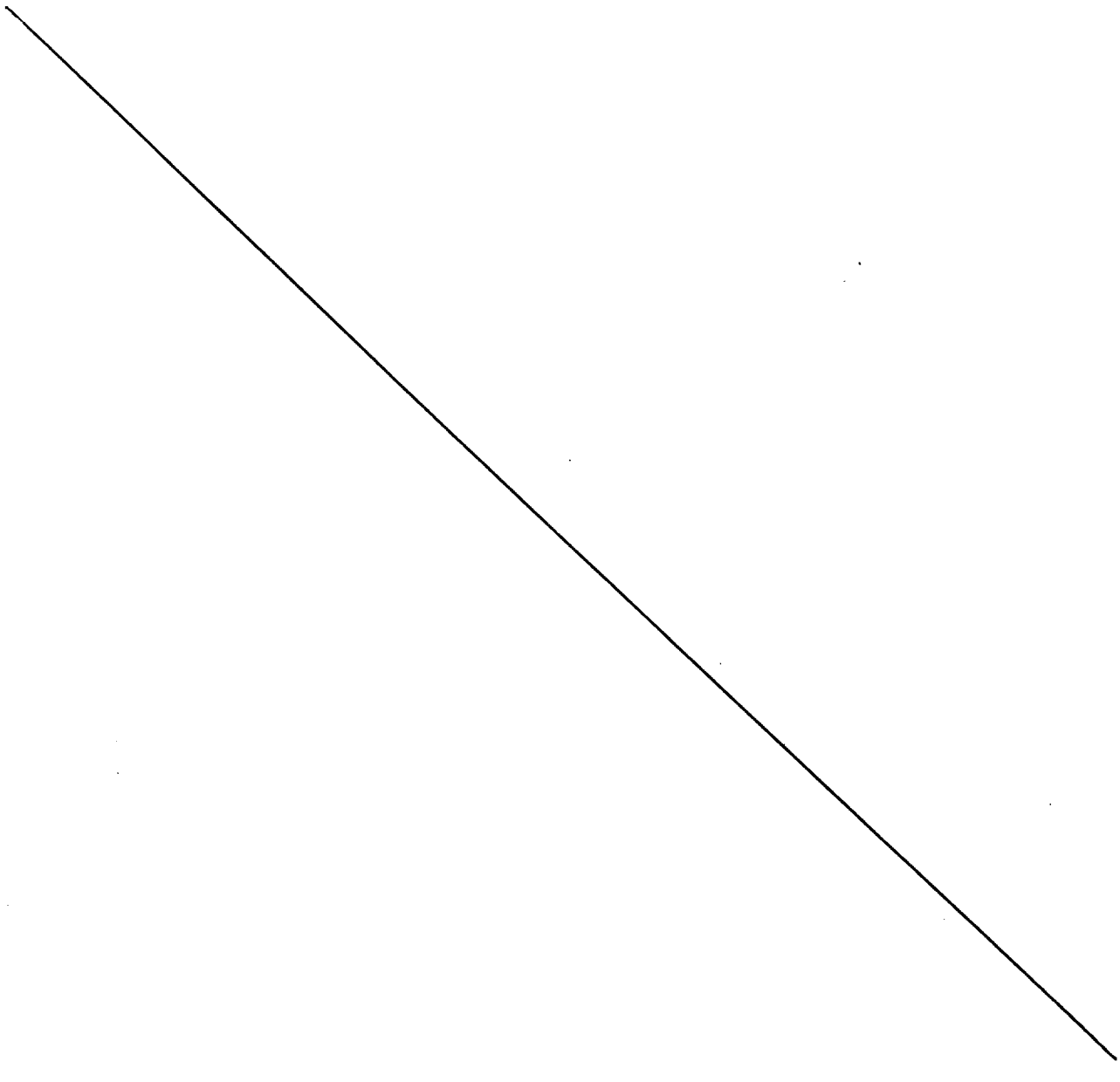
In the **Federal Register** of January 27, 1998 (63 FR 3907), FDA published this guidance in draft form, giving interested persons until March 30, 1998, to submit comments. After consideration of comments received, a final draft guidance was submitted to the VICH Steering Committee.

At a meeting held on October 20 through 22, 1998, the VICH Steering Committee endorsed the draft guidance for industry entitled "Validation of Analytical Procedures: Methodology." This guidance discusses common analytical procedures and provides guidance and recommendations on how to consider the various validation characteristics for each analytical procedure included as part of a registration application for approval of veterinary medicinal products. It also indicated

the various data that should be included in registration applications. This guidance will be implemented in October 1999.

This guidance represents the agency's current thinking on characteristics for consideration during the validation of the analytical procedures included as part of applications. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate approach may be used if it satisfies the requirements of applicable statutes, regulations, or both.

As with all of FDA's guidance, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. The comments in the docket will



be periodically reviewed and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: 7/28/99

July 28, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jan Windsor

Margaret M. Dotzel
Acting Associate Commissioner
for Policy

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F